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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/714,040

11/15/2000

Paul J. Carter

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11/02/2005

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EXAMINER

BLANCHARD, DAVID J

ART UNIT

PAPER NUMBER

1643

DATE MAILED: 11/02/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/714,040

Applicant(s)

CARTER, PAUL J.

Examiner

David J. Blanchard

Art Unit

1643

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 22 August 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 25, 29 and 38-43 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 25, 29 and 38-43 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 8/22/05.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

### **DETAILED ACTION**

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 22 August 2005 has been entered.
2. Claims 1-24, 26-28 and 30-37 are cancelled.  
Claims 25, 29 and 40-41 are presently amended.  
Claim 43 has been added.
3. Claims 25, 29 and 38-43 are pending and under examination.
4. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
5. This Office Action contains New Grounds of Rejections.

### ***Specification***

6. The disclosure is objected to because of the following informalities:  
The specification at page 5, lines 6-7 contain two Glennie et al citations that are incorrect. For example, Glennie et al vol. 141, no. 10, pages 3662-3670 is published in The Journal of Immunology with a publication date of 1988 (see reference 44 on the lds filed 11/15/00). Further, Glennie et al, Journal of Immunology, 139(7):2367-2375, was published on October 1, 1987 (see reference 43 on the lds filed 11/15/00).

Applicant's cooperation is requested in reviewing and correcting any errors of which applicant may become aware in the specification.

Appropriate correction is required.

### ***Rejections Withdrawn***

7. The rejection of claims 25, 29 and 38-39 under 35 U.S.C. 112, second paragraph as being indefinite in the recitation of "disulfide Cys-X-X" is withdrawn in view of the amendments to the claims.

8. The rejection of claims 40-41 under 35 U.S.C. 102(b) as being anticipated by Bodmer et al is withdrawn in view of the amendments to the claims.

### ***Response to Arguments***

9. The rejection of claims 25 and 38 under 35 U.S.C. 102(b) as being anticipated by Bodmer et al (WO 98/01974, 3/9/1989) is maintained.

The response filed 22 August 2005 has been carefully considered, but is deemed not to be persuasive. The response argues that Bodmer does not disclose an amino acid sequence of about 1 to 10 amino acids comprising Cys-X-X, wherein one or both X's are absent or X is Ala, Arg, Pro, or Asp. The response states that Bodmer is directed to using hinge regions that are different in length and/or sequence than that claimed. In response to these arguments, claim 25 as presently amended recites that each Fab' comprises a CH1 domain fused to an amino acid sequence of about 1 to

about 10 amino acids, comprising Cys-X-X, wherein one or both X's are absent or X is Ala, Arg, Pro or Asp and the cysteine of the first Fab' forms a disulfide bond with the cysteine of the second Fab' to form the F(ab')<sub>2</sub>. Bodmer et al teach F(ab')<sub>2</sub> fragments from monoclonal antibodies (i.e., B72.3 Mab) (monospecific) that comprise a CH1 domain fused to a human hinge region or part of a human hinge region (bottom of page 6), wherein the number of cysteine residues in the hinge region is reduced to one (i.e., "free of F(ab')<sub>2</sub> having hinge region intrachain disulfide bonds") by alanine mutagenesis (see pages 2, 6-8, 10, Example 1 at page 10 and Figure 1). In Figure 1, Bodmer shows the sequence of the human hinge regions wherein IgG1, IgG2 and IgG4 are about 10 amino acids in length and comprise the amino acid sequence Cys-Pro, and Cys-Pro-Pro (also see page 10, lines 3-10) and human IgG1, IgG2 and IgG4 hinge regions comprising a single Cys residue read upon the sequence Cys-X-X, wherein both X's are absent. Further, as evidenced by the specification at page 12, lines 6-7, applicant discloses that the hinge region of human IgG1 is about 10 amino acids in length. Thus, the human IgG1, IgG2 and IgG4 hinge regions taught by Bodmer et al and shown in Figure 1 are reasonably interpreted to be about 10 amino acids in length. Applicant is again reminded that the amino acid sequence of about 1 to 10 amino acids "comprises" Cys-X-X, which is open claim language and does not exclude additional unrecited elements (i.e., additional amino acids at either or both termini of the sequence Cys-X-X) (see MPEP 2111.03). Thus, the monoclonal F(ab)<sub>2</sub> fragments taught by Bodmer et al anticipate the claims.

For these reasons the rejection is maintained.

***New Grounds of Rejections***

10. Claims 25, 29 and 38-43 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims are ambiguous in the recitation of "first and second Fab', each first and second F(ab')" in claim 25 and "first and second F(ab'), wherein each first and second Fab" in claim 40. It is unclear is meant by a F(ab') and Fab' and it is unclear if they are the same or different structures. The specification does not appear to disclose or define a F(ab'). As written, one of skill in the art would not be reasonably apprised of the metes and bounds of the claims.

***Conclusion***

11. No claim is allowed.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to David J. Blanchard whose telephone number is (571) 272-0827. The examiner can normally be reached at Monday through Friday from 8:00 AM to 6:00 PM, with alternate Fridays off. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms, can be reached at (571) 272-0832. The official fax number for the organization where this application or proceeding is assigned is 571-273-8300. Any inquiry of a general nature, matching or filed papers or relating to the status of this application or proceeding should be directed to Tony Parks for Art Unit 1643 whose telephone number is 571-272-0543.

Art Unit: 1643

Information regarding the status of an application may be obtained from the patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Respectfully,  
David J. Blanchard  
571-272-0827



LARRY R. HELMS, PH.D.  
SUPERVISORY PATENT EXAMINER